**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF TEXAS**
**MARSHALL DIVISION**

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| ALLERGAN, INC., | § | |
| | § | |
| *Plaintiff*, | § | |
| | § | |
| v. | § | Case No. 2:16-cv-1447-WCB |
| | § | |
| DEVA HOLDINGS A.S., | § | |
| | § | |
| *Defendant*. | § | |
| | § | |

**ORDER**

Before the Court is the motion by defendant Deva Holdings A.S. ("Deva") for entry of final judgment and dismissal with prejudice. Dkt. No. 55. Plaintiff Allergan, Inc. ("Allergan") has not filed a response to the motion, but the Court has treated Allergan's position set forth in the parties' joint status report, Dkt. No. 54, as its response. The motion is GRANTED.

1. On February 22, 2018, the parties moved for an order "(1) staying this case ('the Deva case') pending the outcome of the related appeal to the United States Court of Appeals for the Federal Circuit in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:15-cv-1455-WCB (E.D. Tex.), Case No. 2018-1130 (Fed. Cir.) ('the lead case'); (2) binding the parties on the outcome of that related appeal in the lead case; and (3) requesting that FDA terminate the 30-month stay of the FDA's approval of Deva's ANDA in the Deva case." Dkt. No. 50, at 1.

On March 6, 2018, this Court entered an order granting in part the parties' joint motion to stay the proceedings in this case. Dkt. No. 51. In that order, the Court entered a stay of proceedings in this case pending the outcome of the appeal in the lead case, based on the parties' agreement that the result of that appeal would be binding on the parties in this case. The parties had stipulated

that the stay should extend until the Federal Circuit issued its mandate in Case No. 2018-1130 or otherwise terminated the appeal, and that Allergan and Deva would be bound by the results of the appeal in Case No. 2018-1130 and any proceedings on remand, as necessary. *See* Dkt. No. 50-1. The Court adopted those stipulations in its order. Dkt. No. 51. With respect to the joint request that the Court order the FDA to terminate the 30-month stay of approval of Deva's ANDA, however, the Court expressed doubt as to its authority to order the FDA to terminate the 30-month stay. The Court indicated that the parties could renew their motion if accompanied by a memorandum of law supporting the Court's authority to issue such a directive to the FDA, a non-party in either case. Dkt. No. 51.

Deva responded to this Court's invitation by filing a Renewed Unopposed Motion Requesting Termination of the 30-Month Stay of FDA Approval and Memorandum of Law in Support Thereof. Dkt. No. 52. In the motion, Deva explained that the parties had agreed that the substantive (non-settlement) outcome of the lead case appeal would be binding on the parties in the Deva case. Deva added that Allergan had agreed not to assert against Deva's ANDA any claims of the patents in suit in the lead case other than those invalidated in the lead case, and that Deva had agreed that "should the Federal Circuit affirm or reverse, in whole or in part, this Court's finding of invalidity, that judgment (and any judgment on remand, if necessary) will be binding on Allergan and Deva in this case as if Deva were a party to the appeal." Dkt. No. 52, at 3. "The practical effect" of the agreement, Deva explained, "is that Deva is now similarly situated with the defendants in the lead case." *Id.* Citing 21 U.S.C. § 355(j)(5)(B)(iii) and certain FDA regulations, Deva argued that the Court is authorized to direct that the 30-month stay period be terminated in appropriate circumstances. *Id.* at 4–5.

The Court entered an order denying Deva's renewed motion. The Court noted that nothing in the statute cited by Deva authorizes the Court to order the FDA to terminate the stay of Deva's ANDA. The Court explained that the statute authorizes FDA action; it does not authorize the Court to order the FDA to act. Likewise, the Court pointed out that the regulations cited by Deva do not authorize such action by the Court. The first regulation on which Deva relied, 21 C.F.R. § 314.107(b)(3)(vi), states that the FDA may terminate the stay and grant approval of an ANDA under particular circumstances, but the regulation is addressed to the FDA, not the court. The second regulation, 21 C.F.R. § 314.107(b)(3)(vii), provides that the FDA may terminate the 30-month stay and grant approval of an ANDA if "the court enters an order requiring [the stay] to be terminated," but it does not provide authorization for a court to enter such an order or specify the circumstances under which a court may enter such an order.

2. On November 13, 2018, the Federal Circuit affirmed the judgment entered by this Court in *Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, Case No. 2:16-cv-1455-WCB (E.D. Tex.), and on March 6, 2019, the Federal Circuit denied the appellants' petition for rehearing and rehearing *en banc*. The Federal Circuit issued its mandate in Case No. 2018-1130 on March 13, 2019. The appellants in that case have since filed a petition for a writ of certiorari with the United States Supreme Court seeking review of the Federal Circuit's judgment in that case. *See* Petition for Writ of Certiorari*, Allergan, Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 18-1289 (filed Apr. 10, 2019).

Pursuant to a directive of this Court issued as part of the March 8, 2018, order staying the proceedings in this case, the parties filed a joint status report on April 9, 2019, in which they set forth their respective positions regarding how the Court should proceed regarding the entry of judgment in this case. Allergan agreed to have judgment in this case entered now, but requested

that the judgment be "subject to the outcome of any petition for a writ of certiorari and any proceedings on remand." Dkt. No. 54, at 3. That judgment, according to Allergan, "will allow Deva to request that the FDA lift the 30-month stay" of the approval of Deva's abbreviated new drug application, *see* 21 U.S.C. § 355(j)(5)B)(iii). Allergan argued in the status report that unless the Court adds to its judgment a proviso making the entry of the judgment subject to the outcome of the appellants' petition for certiorari in case number 18-1289, Deva would gain an advantage over the defendants in the lead case, who would be subject to further proceedings on the appellants' petition for a writ of certiorari before the Supreme Court, while Deva would not be.

In its portion of the status report, Deva responded that the joint stay request referred only to the mandate of the Federal Circuit and not to any subsequent proceedings before the Supreme Court. For that reason, Deva argued, the stay issued in this case should be understood to have expired as of the issuance of the mandate by the Federal Circuit in the lead case. Deva added that "prejudice to Deva is built in to Appellants' proposal," because the final judgment in the lead case was not made contingent on proceedings on a writ of certiorari, and a stay of the effectiveness of the judgment entered by the Court would qualify as a final judgment under Fed. R. Civ. P. 58. Dkt. No. 54, at 6–7. Deva argued that it "wants it to be ultimately clear to the FDA that entry of a judgment consistent with the judgment in the lead case satisfies the requirements of 21 U.S.C. § 355(j)(5)(B)(iii) and that the FDA may immediately approve Deva's ANDA, should all of the other statutory and regulatory requirements be met." Dkt. No. 54, at 7 n.2.

On the same day that the parties filed the joint status report, Deva filed the present motion for entry of final judgment. Allergan did not file a response to that motion. As noted, however, the Court has treated Allergan's statement of its position in the joint status report as its response to Deva's motion.

3. The parties' stipulation was addressed to the proceedings in the appeal to the Federal Circuit in the lead case. No provision in the parties' stipulation addressed the effect that a petition for a writ of certiorari would have on the parties' agreement or any action by the Court pursuant to that agreement. By its terms, however, the agreement (and the Court's order entered pursuant to that agreement) contemplated that the Court could enter a final judgment in the Deva case after the Federal Circuit "in the lead case appeal, Case No. 2018-1130, issues its mandate or otherwise terminates the appeal." Dkt. No. 50-1, at 2; Dkt. No. 52, at 2. That has occurred, and Allergan agrees that the Court may now enter its judgment in this case, and that the entry of the judgment "will allow Deva to request that FDA lift the 30-month stay." Dkt. No. 54, at 3.

The wrinkle, however, is that Allergan wants the judgment to be "subject to the outcome of any petition for a writ of certiorari and any proceedings on remand, as necessary." Allergan adds that if its petition for a writ of certiorari in the lead case is granted and the Federal Circuit's decision is reversed or vacated, the judgment in this case should likewise be vacated, and the Court should order "that this case shall be reopened for further proceedings consistent with proceedings in the lead case." *Id.* at 4.

Nothing in the record indicates that the parties' stipulation specifically adverted to the consequences that would flow if a petition for a writ of certiorari were filed in the lead case following the issuance of the Federal Circuit's mandate. There is therefore no basis in the parties' agreement for the Court to make the judgment in this case expressly "subject to the outcome of any petition for a writ of certiorari and any proceedings on remand, as necessary," as Allergan appears to advocate. Dkt. No. 54, at 4. Indeed, it is not entirely clear what such language would mean. There is thus force to Deva's concern that such language in the judgment might raise a question whether the order is a valid final judgment under Fed. R. Civ. P. 58, and it could raise a

question whether the order would be sufficient to authorize the FDA to approve Deva's ANDA. In effect, what Allergan is requesting is that the judgment in this case be entered, but that it be made expressly subject to a condition subsequent that the judgment will be vacated if the Federal Circuit's judgment in the lead case is reversed or vacated. Allergan has cited no authority for issuance of a such a conditional judgment, and the Court is aware of none. The Court therefore declines Allergan's invitation to enter such a conditional judgment.

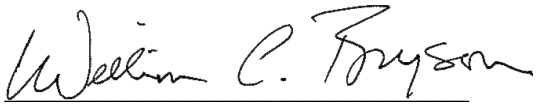
Importantly, however, the use of such unconventional language in the judgment is not necessary. The stipulation entered by the parties regarding the judgment in this case provides protection against the untoward consequences that Allergan has pointed to in the event the Supreme Court should grant certiorari and vacate or reverse the judgment of the Federal Circuit in the lead case. If the Supreme Court should vacate or reverse the judgment of the Federal Circuit in the lead, it would remand to the Federal Circuit (and ultimately to this Court) for further proceedings, as necessary, consistent with the Supreme Court's judgment. The outcome of such subsequent proceedings can fairly be considered to fall within the meaning of the parties' stipulation to be bound "by the results of the appeal in the lead case, Case No. 2018-1130, and any proceedings on remand, if necessary." Dkt. No. 50-1, at 2. If such subsequent proceedings should ultimately result in a judgment different from the one entered by this Court and affirmed by the Federal Circuit in Case No. 2018-1130, a motion for relief from the judgment in this case pursuant to Fed. R. Civ. P. 60(b)(6) would be appropriate.

Accordingly, the Court will grant Deva's motion for entry of a final judgment dismissing the action, on the terms requested by Deva. The entry of the judgment will not be subject to the express condition proposed by Allergan. As to when and under what circumstances the FDA will deem the 30-month stay to be terminated, that is a matter for the FDA to determine. If Allergan

or any of the other parties in the lead case or this case wish to challenge the FDA's ultimate decision regarding the termination of the 30-month stay in these two cases, the proper course would be for the party to seek injunctive relief directed at the FDA. *See Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, Nos. 2009-1427 et al., 2009 WL 7365766, at *2 (Fed. Cir. Aug. 13, 2009) (Moore, J., concurring in the denial of reconsideration).

IT IS SO ORDERED.

SIGNED this 30th day of April, 2019.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE